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Revision 0

DOE Regulatory Unit Evaluation Report of the BNFL Inc. Quality Assurance Program and Implementation Plan

May 1998

Office of Radiological, Nuclear, and Process
Safety Regulation of TWRS Privatization Contractors

Richland Operations Office
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PREFACE

The Department of Energy's (DOE) Richland Operations Office (RL) issued the TWRS Privatization Request for Proposal (RFP) for Hanford Tank Waste Remediation System (TWRS) Privatization in February 1996. Offerors were requested to submit proposals for the initial processing of the tank waste at Hanford. Some of this radioactive waste has been stored in large underground storage tanks at the Hanford Site since 1944. Currently, approximately 56 million gallons of waste containing approximately 240,000 metric tons of processed chemicals and 250 mega-curies of radionuclides are being stored in 177 tanks. These caustic wastes are in the form of liquids, slurries, saltcakes, and sludges. The wastes stored in the tanks are defined as high-level radioactive waste (10 CFR Part 50, Appendix F) and hazardous waste (*Resource Conservation and Recovery Act*).

Under the privatization concept, DOE will purchase waste treatment services from a contractor-owned, contractor-operated facility under a fixed-price contract. DOE will provide the waste feedstock to be processed, and will maintain ownership of the waste. The contractor must: a) provide private financing; b) design the equipment and facility; c) apply for and receive required permits and licenses; d) construct the facility and bring it on-line; e) operate the facility to treat the waste according to DOE specifications; and f) deactivate the facility.

The TWRS Privatization Program is divided into two phases: Phase I and Phase II. Phase I is a proof-of-concept/commercial demonstration-scale effort, the objectives of which are to a) demonstrate the technical and business viability of using privatized contractors to treat Hanford tank waste; b) define and maintain adequate levels of radiological, nuclear, process, and occupational safety; c) maintain environmental protection and compliance; and d) substantially reduce life-cycle costs and time required to treat the tank waste. The Phase I effort consists of two parts: Part A and Part B. Part A consists of a 20-month development period to establish appropriate and necessary technical, operational, regulatory, business, and financial elements. This will include identification by the TWRS privatization contractors and approval by DOE of appropriate safety standards, formulation by the Contractors and approval by DOE of integrated safety management plans, and preparation by the contractors and evaluation by DOE of initial safety assessments. Of the 20-month period, 16 months will be used by the contractors to develop the Part A products and 4 months will be used by DOE to evaluate the products.

Part B consists of a demonstration period to provide tank waste treatment services by one or more of the TWRS privatization contractors who successfully complete Part A. Demonstration will address a range of wastes representative of those in the Hanford tanks. Part B will be 10 to 14 years in duration. Within Part B, wastes will be processed during a 5- to 9-year period and will result in treatment of 6 to 13 percent of the Hanford tank waste.

Phase II will be a full-scale production phase in which the remaining tank waste will be processed on a schedule that will accomplish removal from all single-shell tanks by the year 2018. The objectives of Phase II are to a) implement the lessons learned from Phase I and b) process all tank waste into forms suitable for final disposal.

A key element of the TWRS privatization contracts is DOE regulation of radiological, nuclear, and process safety through the establishment of a specifically chartered, dedicated Regulatory Unit (RU) at RL. This regulation by the RU is authorized by the document entitled *Policy for Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors* (referred to as the Policy) and implemented through the document entitled *Memorandum of Agreement for the Execution of Radiological, Nuclear, and Process Safety Regulation of the TWRS Privatization Contractors* (referred to as the MOA). The Policy is signed by the Under Secretary of Energy; the Manager, RL; the Assistant Secretary for Environment, Safety and Health (ASEH); and the Assistant Secretary for Environmental Management (ASEM). The MOA is signed by the Manager, RL; the ASEH; and the ASEM. The nature and characteristics of this regulation are also specified in these documents. The MOA details certain interactions among RL, the ASEH, and the ASEM as well as their respective roles and responsibilities for implementation of this regulation.

The authority of the RU to regulate the TWRS privatization contractors is derived solely from the terms of the TWRS privatization contracts. The RU's authority to regulate the Contractors on behalf of DOE is derived from the Policy. The nature and scope of this special regulation (in the sense that it is based on terms of a contract rather than formal regulations) is delineated in the MOA, the TWRS privatization contracts, and the four documents (listed below), which are incorporated into the Contracts.

- *Concept of the DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0005,
- *DOE Regulatory Process for Radiological, Nuclear, and Process Safety for TWRS Privatization Contractors*, DOE/RL-96-0003,
- *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for TWRS Privatization Contractors*, DOE/RL-96-0006, and

- *Process for Establishing a Set of Radiological, Nuclear, and Process Safety Standards and Requirements for TWRS Privatization*, DOE/RL96-0004.

This special regulation by the RU in no way replaces any legally established external regulatory authority to regulate in accordance with their duly promulgated regulations nor relieves the contractors from any obligations to comply with such regulations or to be subject to the enforcement practices contained therein.

The Policy, the MOA, the TWRS privatization contracts, and the four documents incorporated in the contracts define the essential elements of the regulatory program, which will be executed by the RU and to which the TWRS Privatization Contractors must conform. In the execution of the regulatory program, the RU will consider not only the relevant approaches and practices of DOE but also those of the Nuclear Regulatory Commission (NRC). The following statement is from the Policy.
"It is DOE's policy that TWRS privatized contractor activities be regulated in a manner that assures adequate radiological, nuclear, and process safety by application of regulatory concepts and principles consistent with those of the Nuclear Regulatory Commission."

To this end, the RU will interact with the NRC (under the provisions of a memorandum of understanding with the NRC) during development of regulatory guidance and during execution of the regulatory program to ensure implementation of this policy.

All documents issued by the Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors are available to the public through the DOE/RL Public Reading Room at the Washington State University, Tri-Cities Consolidation Information Center, Room 101L, 100 Sprout Road, Richland, Washington, 99352.

Executive Summary

This report documents the evaluation of the BNFL, Inc. (BNFL), Quality Assurance Program and Implementation Plan (QAPIP), BNFL-5193-QAP-01. The QAPIP was provided to the U.S. Department of Energy, Richland Operations Office, Office of Radiological, Nuclear, and Process Safety Regulation of Tank Waste Remediation System Privatization Contractors (Regulatory Unit [RU]) as required by the Tank Waste Remediation System Privatization Contract. In addition, the submittal fulfills a commitment made by BNFL in response to RU Question Number 76 on the BNFL Standards Approval Package. Specifically, BNFL responded to this question by proposing to submit the Part B QAPIP to the RU 60 days before Part B contract award.

Revision 3 of the QAPIP was submitted to the RU on March 26, 1998. The comments on Revision 3 were discussed with BNFL staff at a working meeting on April 3, 1998, and formally transmitted to BNFL on April 27, 1998 (Gibbs 1998). BNFL responded to the RU comments on Revision 3 of the QAPIP with a draft Revision 4, provided to the RU the week of April 20, 1998. The draft Revision 4 substantially addressed the RU comments regarding Revision 3.

Comments developed as a result of the RU review of the draft Revision 4 of the QAPIP were discussed and resolved with BNFL on April 30, 1998, during a meeting that was open to the public.[1] BNFL formally submitted the final Revision 4 of the QAPIP to the RU the week of May 11, 1998.

The RU has reviewed the BNFL Revision 4 of the QAPIP and recommends that the Regulatory Official approve the QAPIP, subject to the following conditions:

- The implementing documents and procedures identified in Table A-1 of Appendix A, and required prior to start of preliminary design, detailed design, and procurement, shall be issued before the start of those respective phases of project activity.

- BNFL shall implement the BNFL 5193-QAP-01, Revision 4, as approved by the RU, for Part B activities up to the start of construction.

[1] Meetings that involve discussions between the RU and a contractor leading to a decision, where protected information is not discussed, are open to the public. Meetings are “open” to assure that public that no special consideration is being given to the contractor. Open meetings also allow the public to observe the regulatory process.

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DOE Regulatory Unit Evaluation Report of the BNFL Inc. Quality Assurance Program and Implementation Plan

1.0 Introduction and Purpose

The BNFL quality assurance program descriptions for Part A activities (BNFL-5193-QAP-01, Rev. 0, 1 and 2) were submitted to the U.S. Department of Energy (DOE), Richland Operations Office (RL), Office of Radiological, Nuclear, and Process Safety Regulation of TWRS Privatization Contractors (Regulatory Unit [RU]) in late 1996 and early 1997. The *Evaluation Report for the BNFL Inc. Initial Quality Assurance Program* RL/REG-97-01, January 1997, documents the RU evaluation of the BNFL QAP. This evaluation demonstrated that the BNFL QAP complies with the requirements of 10 CFR 830.120. However, the QAP only considered Part A activities. It was not clear to the reviewers when a Part B QAP and its implementation plan would be submitted to the RU.

In response to RU Question Number 76 on the BNFL Standards Approval Package, BNFL committed to submit the Part B QAP and Implementation Plan (QAPIP) to the RU 60 days before Part B contract award. This report documents the RU's evaluation of the BNFL *Quality Assurance Program and Implementation Plan*, BNFL-5193-QAP-01. Rev. 3 and 4.

2.0 Review Process

2.1 Review Approach for the Quality Assurance Program and Implementation Plan

The RU assembled a four-person review team to evaluate the BNFL QAPIP. The review team composition and expertise are presented in Section 2.3 of this report. In addition to the RU review team, Mr. J. G. Spraul of the Nuclear Regulatory Commission (NRC) provided input and comments on the QAPIP for the review team's consideration. Messrs. C. K. Kasch and J. L. Pfeiffer of the Quality Programs Team in the RL Office of Environment Safety and Health informally reviewed the document against Hanford Site experience. Their comments were discussed with BNFL and resolution was included in Revision 4.

The reviewers systematically evaluated the BNFL QAPIP using guidance established in the following documents:

- 10 CFR 830.120, "Quality Assurance Requirements," *Code of Federal Regulations*
- G-830.120, Revision 0, *Implementation Guide For Use With 10 CFR Part 830.120 Quality Assurance*
- RL/REG-96-01, Revision 0, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program.*

The review team's evaluation of the QAPIP was provided to BNFL in writing and verbally through meetings.

To shorten the review cycle and increase review efficiency, the review approach included open meetings between the review team and BNFL to discuss each comment. These discussions were intended to accomplish the following:

- Ensure clear understanding of the comment
- Ensure acceptance of the comment, or withdrawal of the comment, if incorrect
- Allow discussion of possible resolution(s)
- Allow BNFL to establish a specific resolution where possible.

This approach eliminated misunderstandings associated with written comments and reduced the time lost in restating and resubmitting comments.

2.2 Review Chronology for the Quality Assurance Program and Implementation Plan

The major milestones throughout the review period are shown in Table 2.2-1.

Table 2.2-1. Chronology of BNFL QAPIP Review.

Milestone	Date 1998
Revision 3 of the QAPIP received from BNFL	March 26
Comments regarding Revision 3 of the QAPIP received from NRC	April 3
RU comments regarding Revision 3 of the QAPIP presented at working meeting with BNFL	April 3
RU written comments regarding Revision 3 of the QAPIP provided informally to BNFL	April 17
Draft revision 4 of the QAPIP received from BNFL	April 22
RU written comments regarding Revision 3 of the QAPIP formally provided to BNFL	April 27
RU comments regarding draft Revision 4 of the QAPIP discussed at open meeting	April 30
Revision 4 of the QAPIP formally received from BNFL	May 15

2.3 Team Composition and Expertise

Table 2.3-1 provides the names, level of education, and expertise of the QAPIP review team under the leadership of Mr. Albert Hawkins.

Table 2.3-1. Review Team Membership Education and Expertise.

QAPIP Review Team Member	Education/Expertise
Albert Hawkins	B.S. Chemical Engineering, MBA. More than 25 years experience in operations, oversight, safety, and quality assurance. Former Manager of Compliance Assurance and Director of Environment, Safety, Health and Quality Assurance.
Thomas Colandrea, P.E.	B.S. Metallurgical Engineering, M.S. Engineering Science and Metallurgy, MBA, P.E. (California). ASQ Certified Quality Engineer, Reliability Engineer, and Quality Auditor; ANSI/ASME NQA-1 Lead Auditor; ISO 9000 Certified Lead Auditor; ASQ Fellow. 35 years experience in Nuclear QA and metallurgical engineering.
Sandra English	B.S. in Medical Technology, 15 years in QA with expertise in requirements for EPA, FDA, DOE, and Nuclear Industry. ASQ Certified Auditor with more than 75 audits completed.
Richard Stephans, P.E., C.S.P., C.E.M.	B.S. Ch.E. Purdue, M.S. M.E.; System Safety Society Fellow; Co-Editor, *System Safety Analysis Handbook*; ANSI/ASME NQA-1 Lead Auditor/Trainer/Certifier; 30 years experience and expertise in safety/risk analysis, chemical engineering, nuclear QA, emergency management, and chemical process safety.

3.0 Findings

3.1 Comments Regarding Revision 3 of the QAPIP

The RU reviewers generated 149 comments in the evaluation of Revision 3 of the BNFL QAPIP. These comments varied in importance from the primary issues shown in Table 3.1-1 to a large number of less significant issues. The comments were formally provided to BNFL (98-RU-0144). Also shown in Table 3.1-1 is the resolution proposed by BNFL regarding each primary issue as reflected in Revision 4 of the QAPIP.

Table 3.1-1 Primary Issues and Their Resolution Regarding the Revision 3 QAPIP

Summary of Primary Issue	Resolution by BNFL
Contrary to requirements of 10 CFR 830.120, the QAPIP lacked adequate detail in describing the methods and systems for achieving quality and identifying specifically how the applicable QA requirements are to be satisfied.	BNFL significantly expanded the level of detail in the QAPIP to describe how the applicable QA requirements pertaining to the pre-construction Part B activities will be satisfied.
The wording of the QAPIP restricted its application to the "design stage," leaving a gap in coverage regarding those activities other than design that will take place before the start of construction (e.g., procurement).	BNFL revised the wording of the QAPIP in a manner that makes it clear that this document applies to all activities up to the start of construction.
Descriptions in the QAPIP were inconsistent regarding the QA requirements documents that BNFL will comply with and implement during Part B.	BNFL clarified the QAPIP by indicating that it meets the requirements of 10 CFR 830.120. However, as discussed in Section 3.2 of this evaluation report, draft Revision 4 of the QAPIP did not adequately reflect the contractual requirements regarding DOE/RW-0333P and NUREG-1293.
In RL/REG-97-01, *Evaluation Report for the BNFL Inc. Initial Quality Assurance Program*, Section 4.1 suggested 15 modifications. Many of these were not implemented.	BNFL addressed the majority of the suggested modifications. However, as discussed in Section 3.4 of this evaluation report, three of the modifications were not reflected in draft Revision 4 of the QAPIP.
The description of the Quality Levels (QL) and associated quality assurance (QA) requirements lacked adequate clarity and completeness.	BNFL improved the clarity of the definition of each Quality Level, described the relationship between Quality Levels and safety classifications, and included a tabular summary showing the application of QA requirements for QL-1, QL-2, and QL-3 SSCs. However, as discussed in Section 3.2, the tabular summary in the draft Revision 4 of the QAPIP was inconsistent with previous versions of this table submitted by BNFL to the RU.
The QAPIP indicated that a list of the Important-to-Safety structures, systems, and components (SSCs) would be developed during the detailed design stage. Concern was expressed as to how staff will know the level of quality to apply to activities during the initial design stage.	As discussed in Section 3.2, below, BNFL did not adequately address this issue in draft Revision 4 of the QAPIP.
The hierarchy of QA documents was not clear.	BNFL substantially expanded the explanation of the hierarchy of QA documents in draft Revision 4 of the QAPIP.
The QAPIP appeared to place what could become unreasonable limitations on the TWRS Privatization Project QA Manager's use of stop work authority.	BNFL revised the wording in draft Revision 4 of the QAPIP to provide the TWRS Privatization Project QA Manager with adequate stop work authority.
The QAPIP required amplification and clarification of the process that the TWRS Privatization Project uses to ensure personnel are appropriately trained and qualified.	BNFL expanded draft Revision 4 of the QAPIP to explain the training and qualification process more clearly.

Table 3.1-1 Primary Issues and Their Resolution Regarding the Revision 3 QAPIP

Summary of Primary Issue	Resolution by BNFL
The purpose paragraph of the QAPIP section on design did not address "planning."	BNFL revised Section 6.1, "Purpose" of draft Revision 4 to include planning.
The QAPIP did not specify that QL-1 and QL-2 items are to be reviewed by the QA organization.	BNFL significantly expanded the design and other sections of the draft Revision 4 of the QAPIP to include QA review of items important to safety.
Section 6.2.4 of the QAPIP (configuration management) lacked sufficient information to judge conformance with 10 CFR 830.120.	BNFL expanded the configuration management section of the draft Revision 4 of the QAPIP to be in conformance with 10 CFR 830.120.
The timing of design verification stated in Section 6.2.7 of the QAPIP was inconsistent with 10 CFR 830.120.	BNFL clarified the wording of the draft Revision 4 of the QAPIP such that the intent of 10 CFR 830.120 regarding the timing of design verification is met.
The QAPIP did not adequately describe design verification to include how BNFL differentiates between documents that undergo formal design review/verification by interdisciplinary or multi-organizational teams and those that can be reviewed by a single individual.	BNFL extensively updated the design section of the draft Revision 4 of the QAPIP. (The detail of specifically who and how the verification will be accomplished awaits publication in implementing procedures.)
The QAPIP stated that suppliers will be "monitored" every three years, rather than "audited," as required.	BNFL changed the procurement portion of the draft Revision 4 of the QAPIP to specify that suppliers will be audited at least every three years.
The QAPIP was unclear as to whether procurement documents shall specify acceptance criteria.	BNFL significantly enhanced the procurement section of the draft Revision 4 of the QAPIP to clarify that procurement documents shall specify acceptance criteria.
The QAPIP Inspection and Acceptance Testing section did not address the element of identifying acceptance criteria.	BNFL expanded the content of the acceptance testing section of the draft Revision 4 of the QAPIP to include acceptance and rejection criteria.
The QAPIP section on management assessments did not appear to fully respond to the 10 CFR 830.120 requirement that "management shall assess their management processes."	BNFL added the requirement for assessing management processes to the draft Revision 4 of the QAPIP.
BNFL provided several terms whose definitions were not in accordance with the definitions in 10 CFR 830.3 or RL/REG-96-0006. Although BNFL had proposed these changes in a separate action, such definition changes were not approved by the DOE.	BNFL modified the draft Revision 4 of the QAPIP glossary to reflect the 10 CFR 830.3 and RL/REG-96-0006 definitions.
The implementation plan appendix of the QAPIP did not discuss the QA implementation requirements of ANSI/ASME NQA-1, DOE/RW-0333P, or NUREG-1293.	Although BNFL did not provide the implementation requirements of the three subordinate standards in the QAPIP, this information is expected to be in the Part B implementing procedures.

3.2 Comments Regarding Draft Revision 4 of the QAPIP

As stated in Section 3.1, BNFL responded to the RU comments regarding Revision 3 of the QAPIP with a revised QAPIP (draft Revision 4). The changes reflected in draft Revision 4 addressed most of the Revision 3 comments. Table 3.1-1 notes the primary issues resulting from the Revision 3 review. However, five primary issues and several less significant comments were noted by the RU during the review of the draft Revision 4 of the QAPIP. Table 3.2-1 summarizes these primary issues and the resolution achieved on each at the April 30, 1998, open meeting between the RU and BNFL staff. In addition to resolving these five issues at this meeting, the review team and NRC representative worked with the BNFL staff to resolve other outstanding issues regarding the QAPIP. A second draft of the Revision 4 of the QAPIP was subsequently reviewed by the RU and NRC and adequately reflected closure on nearly all issues. The few remaining issues were relatively minor and readily resolved, with resolution reflected in the final Revision 4 of the QAPIP.

Table 3.2-1 Primary Issues and Their Resolution Regarding the Draft Revision of the QAPIP

Summary of Primary Issue	Resolution Achieved at April 30 Meeting
The wording of Section 1.2 of the QAPIP was confusing regarding the extent to which ANSI/ASME NQA-1, DOE/RW-0333P, and NUREG-1293 will be applied during Part B.	BNFL revised the wording of Section 1.2 to clarify that they will comply with applicable elements of ANSI/ASME NQA-1, RW-0333-P, and NUREG-1293 during Part B.
The QAPIP indicated that a list of the Important-to-Safety SSCs would be developed during the detailed design stage. The reviewers could not determine how staff would know the level of quality to apply to activities during the initial design stage.	Section 1.2.1 was revised to indicate that a list of Safety Design Class and Safety Design Significant SSCs will be developed and maintained during the preliminary design stage.
Table 1-2, "Application of QA Program Requirements for QL-1, 2, and 3 SSCs," was inconsistent with previous versions submitted by BNFL to the RU. Specifically, the use of "should" instead of "shall" and the definition for legends at the end of the table were different.	BNFL modified the table to address these inconsistencies.
Figure 1-2, "Quality Program Document Hierarchy and Relationship," was not consistent with related text. (The RU noted that the table was a valuable addition to the QAPIP.)	BNFL changed the figure and text to be consistent.
The reviewers believed Appendix A required clarification regarding the implementation procedure development schedule.	BNFL confirmed that all procedures in the preliminary design column of Table A-1 would be completed and issued within 30 days after notice to proceed into Part B. The reviewers withdrew this issue.

3.3 Text Deletions

In addition to the issues discussed in Section 3.2, the review team noted that several important statements in Revision 3 of the QAPIP were deleted from the draft Revision 4 document (Table 3.3-1).

During the April 30, 1998, meeting, the review team expressed concern to BNFL regarding these deletions as follows.

- Several deletions represented a reduction in the QA-related controls the RU considers important (e.g., deletion of the commitment to take no adverse actions against an employee for identifying a condition adverse to quality; deletion of the commitment to not exceed 12 months between management assessments).

- The deletions limit the RU's ability to review and approve changes to the QAPIP in a timely and visible manner (i.e., the RU should not have to search through the QAPIP to find deleted text that might affect commitments specified in a previous revision of the document).

- The deletions tend to reinforce the concern expressed by the RU regarding the need for BNFL to demonstrate adequate attention to detail during critical aspects of planning, developing, and implementing the QA program.

During the meeting, BNFL agreed that, in the future, they would provide the RU with marked-up text to clearly identify each proposed change to the QAPIP and the reason for that change.

Table 3.3-1 Apparent Text Deletions From the Revision 3 QAPIP and Their Resolution

Summary of Apparent Text Deleted	Resolution Achieved at April 30 Meeting
Section 1.2.2: Instead of clarifying the wording with respect to who performs the verification that the procedures incorporate applicable elements of the QAPIP, BNFL deleted the statement in question.	BNFL reinstated and clarified the wording in this section.
Section 2.3, page 2-2, last paragraph: BNFL deleted the entire paragraph ("Training records and qualification certifications for individuals performing QA-related activities are designated "quality records" and managed as such under the records management program").	BNFL revised the wording of the QAPIP to make it clear that training records and qualification certifications will be retained as "quality records."
Fourth paragraph of Section 3.2: Instead of deleting the few suggested words ("in areas subject to the QAP"), BNFL deleted the entire paragraph ("No adverse actions shall be taken against an employee for identifying a condition, in areas subject to the QAP, that the employee reasonably believes is adverse to quality.").	BNFL reinstated and made satisfactory changes to the wording of this section.
Section 4.2: The commitment to establish a master list "to identify the current revision of controlled documents to preclude the use of nonreplicable or superseded documents" was deleted.	BNFL reinstated the wording to commit to a master list for document control.
Section 6.2.5: In response to a comment about the use of interface controls that avoid or correct conflicts,	BNFL reinstated the deleted text and clarified the use of the word "conflicts."

Table 3.3-1 Apparent Text Deletions From the Revision 3 QAPIP and Their Resolution

Summary of Apparent Text Deleted	Resolution Achieved at April 30 Meeting
the mention of such a system was deleted, rather than clarify the use of the word "conflicts."	
Section 9.2: Rather than changing "should" to "shall" in the sentence, "The maximum period between management assessment should not exceed 12 months," BNFL deleted the sentence.	BNFL reinstated the deleted text and changed "should" to "shall."

3.4 Modifications from Initial QAP

Fifteen modifications to the Part A QAP were identified in RL/REG-97-01. The modifications are also applicable to Part B activities. The review team noted that not all modifications were incorporated in the draft Revision 4 of the QAPIP. The modifications not included and the resolution agreed upon during the meeting on April 30, 1998, are summarized in Table 3.4-1.

Table 3.4-1 Initial QAP Modifications and Their Resolution

Summary of Modification	Resolution Achieved at April 30 Meeting
BNFL should clarify the relationship between the BNFL QAP and the Project QAP.	The organization chart Figure 1-3 was changed to accurately describe the relationship between the project and BNFL.
The QAPIP deleted a requirement to approve records.	The oversight was corrected with the final Revision 4 of the QAPIP.
The QAPIP does not address maintenance of items to include measuring and test equipment used to determine acceptance of items, products, or processes.	BNFL confirmed that it would establish such maintenance requirements in project procedures before use in activities important to safety.

4.0 Recommendations

4.1 Recommendation for Approval

The reviewers recommend that the Regulatory Official approve the QAPIP, subject to the conditions identified in Section 4.2. This recommendation is based on the following determinations:

- The QAPIP complies with 10 CFR 830.120, *Quality Assurance Requirements*, for the work that will be conducted before starting construction of the TWRS Privatization facility.

- The QAPIP is consistent with the guidance established in (a) G-830.120, Revision 0, *Implementation Guide For Use With 10 CFR Part 830.120 Quality Assurance* and (b) RL/REG-96-01, Revision 0, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*, for work that will be conducted before starting construction of the TWRS-P facility.

- The QAPIP recognizes the commitment identified in the contract regarding the application of the *Quality Assurance Requirements and Description for Civilian Radioactive Waste Management Program* (DOE/RW-0333P).

- The QAPIP recognizes the commitment identified in the contract regarding the application of NUREG-1293 to TWRS Privatization activities related to solidified Low Activity Waste.

4.2 Conditions of Approval:

The review team recommends that the following conditions be included with the approval of the BNFL QAPIP:

- The implementing documents and procedures identified in Table A-1 of Appendix A, and required prior to start of preliminary design, detailed design, and procurement, shall be issued before the start of those respective phases of project activity.

- BNFL shall implement the BNFL 5193-QAP-01, Revision 4, as approved by the RU, for Part B activities up to the start of construction.

5.0 Acronyms

CFR	Code of Federal Regulations (CFRs)
DOE	U.S. Department of Energy
NRC	U.S. Nuclear Regulatory Commission
QL	quality levels
QAP	quality assurance program
QAPIP	Quality Assurance Program Implementation Plan
RL	U.S. Department of Energy, Richland Operations Office
RO	Regulatory Official
RU	Regulatory Unit
SRD	Safety Requirements Document

SSCs	structures, systems, and components
TWRS	Tank Waste Remediation System

6.0 References

10 CFR 830.120 Nuclear Safety Management, Part 120, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.

ANSI/ASME NQA-1, 1986, *Quality Assurance Program Requirements for Nuclear Facilities*, American National Standards Institute, New York, New York.

BNFL-5193-QAP-01, 1998, *Quality Assurance Program and Implementation Plan (QAPIP)*, BNFL, Inc., Richland, Washington.

DOE/RW-0333P, 1998, *Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program (QARD)*.

Gibbs, 1998, "RU Comments on BNFL-5193-QAP-01, Rev. 3, "Quality Assurance Program and Implementation Plan (QAPIP)," IMS # 98-RU-0144, Letter 98-RU-B-049 to M. J. Bullock, April 17, U.S. Department of Energy, Richland Operations Office, Richland, Washington.

RL/REG-96-0006, 1996, *Guidance for Review of TWRS Privatization Contractor Initial Quality Assurance Program*, Rev. 0, U.S. Department of Energy, Richland Operations Office, Richland, Washington.

RL/REG-97-01, 1997, *Evaluation Report for the BNFL Inc. Initial Quality Assurance Program*, Rev. 0, U.S. Department of Energy, Richland Operations Office, Office of Radiological, Nuclear, and Process Safety Regulation, Richland, Washington.

G-830.120, Revision 0, Implementation Guide for Use With 10 CFR Part 830.120 Quality Assurance Requirements.